

REMARKS

Reconsideration is respectfully requested of the rejection of claims 30-43 and 45-51 as anticipated by Pourahmadi et al., US Pat. 6,440,725, and of claim 44 as obvious in view of the same reference.

Applicants' claim 30 has been amended to be commensurate in scope with claim 1 of their recently granted European patent EP 1 174 134 B1. The amendments to sections d and e of claim 30 are supported by the original claim 1 of the PCT application PCT/GB2005/000308 (WO 2005/073691) of which this is a US national application. The amendment to require only a single pump or syringe is supported by the text at page 29, lines 17-19.

Claim 30 is directed to a lab-on-a-chip diagnostic system for sample preparation of a fluid sample containing cells and/or particles. As amended, the system has these express requirements:

- 1) There is a mandatory valve controlling flow of liquid between the reservoir for lysis fluid and the lysis unit;
- 2) There is a mandatory valve controlling flow of liquid between the reservoir for eluent and the nucleic acid extraction unit;
- 3) The system is driven by a single pump or syringe; and
- 4) All the components are formed on a common substrate.

While the claimed system is driven by a single pump or syringe, in contrast separate pumping systems are required to drive liquid flow in the apparatus of Pourahmadi et al. For example, the sample under test is introduced into the apparatus of Pourahmadi et al via sample port 103. Lysing agents are released from storage chamber 109, and elution fluid is dispensed from storage region 127:

In operation, a fluid sample containing a desired analyte. e.g. nucleic acid, is added to the sample port 103 of the cartridge 101 and forced to flow continuously (such as with an electrolytic or mechanical pump) down a channel 105 and into the mixing chamber 107. Lysing reagents are simultaneously released from the storage chamber 109 and forced to flow down a channel 111 and into the chamber 107. Pourahmadi et al., Col. 8, line 62 ff.

After washing the component 122, elution fluid from the storage region 127 is forced to flow down channel 131 and through the component 122, thus releasing the nucleic acid from the component into the elution fluid. Pourahmadi et al., Col. 9, line 52 ff.

The sample port 103, lysing agent storage chamber 109, and elution fluid storage region 127 are shown in Pourahmadi et al.'s Fig. 2:

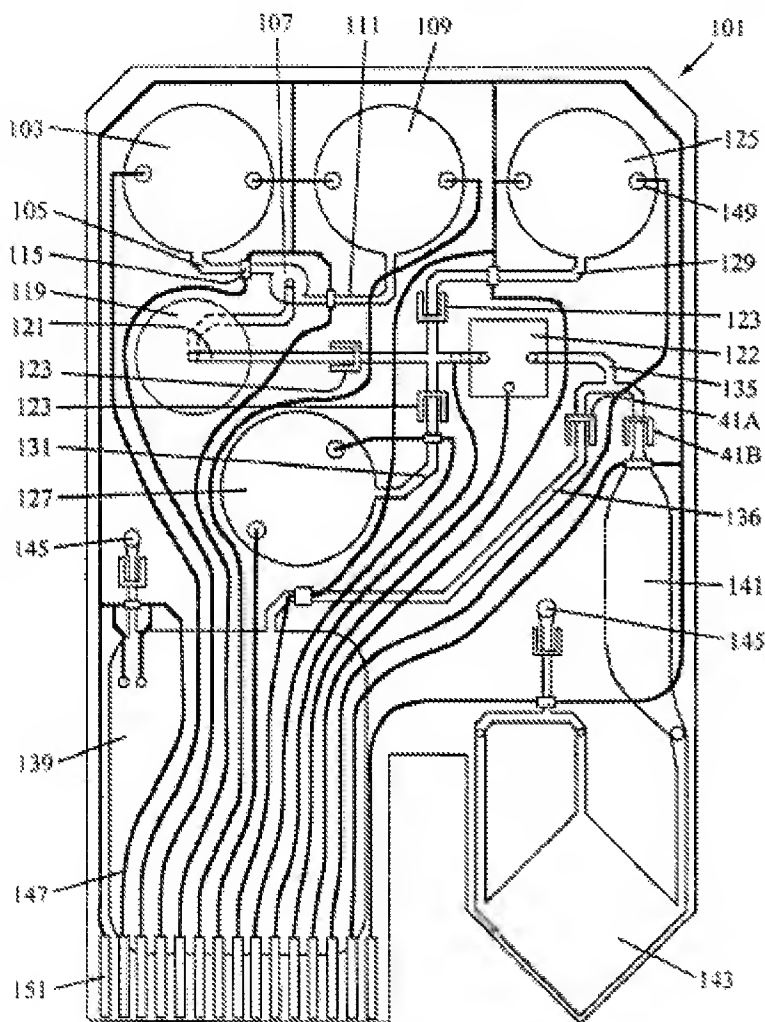


FIG. 2

The lysing agents and elution fluids are not dispensed as a result of pressure generated by a single pumping system. Instead, various fluid motive sources are used to dispense the various reagents, as described in column 8, lines 19-61. These are

described, for example, as applying pressure against an individual reagent pouch, e.g., Col. 8, line 30 and Col. 8, line 39, thereby underscoring that each pouch has its own pumping mechanism. Moreover, as noted at column 9, line 61, "The flow rate of the elution fluid may be relatively low as compared to the flow rate of the fluid sample to allow for more analyte to be released from the component."

The Pourahmadi et al. setup requires a complex system of electrical leads to operate the various "pumps":

The instrument 211 preferably includes processing electronics, e.g., one or more microprocessors, multiplexers, power control circuits, and sensor circuits, for controlling the operation of the cartridge 101. The processing electronics are connected by the contact fingers 151 and electrical leads 147 to various regions, storage areas, pumps, sensors, and channels in the cartridge 101. Pourahmadi et al., Col. 8, line 6 ff.

The device described by Pourahmadi et al. therefore requires multiple pumping systems for the actuation of fluids. The current invention eliminates this complexity, and makes the manufacture and operation substantially more straightforward, by utilizing a system of valves in combination with a single pump or syringe. The features of the device of Pourahmadi et al. could not be driven by a single pump and there is no indication that a single pump could be used in practice. They wholly fail to suggest that their system could have been operated by a single pump; nor even in hindsight is there any technical basis to conclude that their system could have been modified to have been driven by a single pump; nor would one skilled in the art have any expectation of success in implementing such a modification.

In view of the foregoing, therefore, it is respectfully submitted that claim 30 is patentable over Pourahmadi et al. because it is expressly limited to a system having only a "single pump or syringe for actuation of all fluids." Claims 31-51 depend directly or indirectly from claim 30, and are therefore patentable for the same reasons and by virtue of the additional requirements they recite.

CONCLUSION

In view of the foregoing, applicants respectfully request issuance of a Notice of Allowability for all pending claims.

The Commissioner is hereby authorized to charge any deficiency or credit any overpayment of any required fee for this filing to Deposit Account No. 19-1345.

Respectfully submitted,

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